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OFFICE OF PETITIONS

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|---------------------------------|---|---------------------------|
| In re Patent No. 7,498,338 | : | LETTER REGARDING PATENT |
| Vidal Juan, et al. | : | TERM ADJUSTMENT AND |
| Issue Date: March 17, 2009 | : | NOTICE OF INTENT TO ISSUE |
| Application No. 10/509,280 | : | CERTIFICATE OF CORRECTION |
| Filed: May 5, 2005 | : | |
| Attorney Docket No. 09605-.0002 | : | |

This is in response to the "APPLICATINO FOR PATENT TERM ADJUSTMENT - POST GRANT," filed May 15, 2009, requesting that the patent term adjustment determination for the above-identified patent be changed from one hundred fifty-two (152) days to four hundred fifty-nine(459) days. For the reasons set forth herein, the request for reconsideration is being treated as a request that the revised patent term adjustment be corrected one hundred fifty-two (152)days to three hundred and eight(308) days.

The request for reconsideration of patent term adjustment is **GRANTED** to the extent indicated herein.

The patent term adjustment indicated in the patent is to be corrected by issuance of a certificate of correction showing a revised Patent Term Adjustment of **three hundred and eight(308) days**.

Patentees are given THIRTY (30) DAYS or ONE (1) MONTH, whichever is longer, from the mail date of this decision to respond to this decision. No extensions of time will be granted under § 1.136.

On March 17, 2009, the above-identified application matured into U.S. Patent No. 7,498,338 with a patent term adjustment of 152 days.

This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See 1.705(d).

The Office acknowledges receipt of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Patentees request recalculation of the patent term adjustment based on the decision in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to Wyeth, a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays "occur on the same day." Patentees maintain that a portion of the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.703(b), 307 days of the of 316 days, and the period of adjustment due to examination delay, pursuant to 37 CFR §1.702(a), of 377 days do not overlap, as these periods do not occur on the same day.

Patentees argue that the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.702(b), is 316 days. Patentees calculate this 316 day period based on the application having been filed under 35 U.S.C. §371 on May 5, 2005, and the patent having not issued until March 17, 2009, three years and 316 days later.

Patentees are informed that the Three Year Delay period is triggered by the application's commencement date, not the § 371 fulfillment date. The commencement date is 30 months from the priority date claimed in the international application, or earlier. The priority date claimed in the international application is April 1, 2002. Thirty months from that date is October 1, 2004, which is the beginning of the Three Year Delay period. Accordingly, the period of adjustment under § 1.702(b) is 533 days, counting the number of days beginning on October 2, 2007 and ending on March 17, 2009 when the patent issued.

Patentees assert that in addition to the three year delay period, they are entitled to a period of adjustment due to examination delay, pursuant to 37 CFR §1.702(a), totalling 377 days. This 377 day period is the sum of:

- a period of delay of 237 days for the failure by the Office to mail at least one of a notification under 35 U.S.C. 132 not later than fourteen months after the

date the application fulfilled the requirements of 35 U.S.C. 371 in an international application, pursuant to § 1.702(a)(1);

- a period of delay of 131 days for the failure by the Office to respond to a reply under 35 U.S.C. 132 not later than four months after the date on which the reply was filed, pursuant to § 1.702(a)(2); and
- a period of delay of 9 days for the failure by the Office to respond to a reply under 35 U.S.C. 132 not later than four months after the date on which the reply was filed, pursuant to § 1.702(a)(2);

Under 37 CFR § 1.703(f), Patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR §1.702 reduced by the period of time equal to the period of time during which Patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR §1.704. In other words, the period of Office delay reduced by the period of applicant delay. The period of reduction of 225 days for applicant delay is not in dispute. Patentees assert that the total period of Office delay is the sum of the period of Three Year Delay (316 days per patentees' calculation) and the period of Examination Delay (377 days, not in dispute) **to the extent that these periods of delay are not overlapping.**

Patentees contend there is a nine (9) day period of overlap. Patentees argue the entire 9 day period from October 23, 2008 to October 31, 2008 overlaps with a portion of the three year delay period, from May 6, 2008 to March 17, 2009. However, as discussed above, the Three Year Delay period is from October 2, 2007 to March 17, 2009. Therefore, applying patentees' definition of overlap, the period of delay of 131 days for the failure by the Office to respond to a reply under 35 U.S.C. 132 not later than four months after the date on which the reply was filed, pursuant to § 1.702(a)(2), (October 26, 2007 to March 4, 2008) overlaps with a portion of the Three Year Delay period (October 2, 2007 to March 17, 2009), also. This overlapping period is the entire 131 day period. Considering that the three-year period is properly calculated based on the commencement date and is 533 days, not 316 days, and that the period of overlap is 140 (131 + 9) days, applying patentees' definition of

overlap to the correct three-year period, patentees' assertion of the total period of Office delay is considered to be 770 days, which is the sum of the period of Three Year Delay (533 days) and the period of Examination Delay (377 days), reduced by the period of overlap (140 days).

Considering that the three-year period is properly calculated based on the commencement date and is 533 days, not 316 days, and that the period of overlap is 140 days, applying patentees' definition of overlap to the correct three-year period, patentees' assertion of entitlement to a patent term adjustment is considered to be 545 days (533 + 377 reduced by 140 overlap - 225 for applicant delay).

As discussed above, the Office states that the patent issued 3 years and 533 days after the application's commencement date. The Office agrees that the actions detailed above were not taken within the specified time frames, and thus, the entry of period of adjustment of 377 days is correct. At issue is whether Patentees should accrue 393 (adjusted for overlap, per patentees' definition of overlap and Office's calculation of the Three Year Delay Period) days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as, 377 days for Office failure to take certain actions within specified time frames (or examination delay).

The Office contends that 377 days overlap. Patentees' interpretation of the period of overlap has been considered and found to be incorrect. Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the

actual number of days the issuance of the patent was delayed.

As explained in *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 54366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule*, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation

of 35 U.S.C. 154(b)(2)(A). As stated in the *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding §1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3 year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718¹

As such, the period for over 3 year pendency does not overlap only to the extent that the actual dates in the period beginning

¹ The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106th Cong. 1st Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999) (daily ed. Nov. 17, 1999).

three years after the commencement date overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the commencement date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period from the application's commencement date through the date it matured into Patent No. 7,504,398, October 1, 2004 to March 17, 2009. (There were no periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)).

Therefore, 156 days, not 0 days, of patent term adjustment should have been entered for the Three Year Delay period, since the period of delay of 533 days attributable to the delay in the issuance of the patent overlaps with the adjustments of 377 days attributable to the grounds specified in § 1.702(a)(1) and § 1.702(a)(2). 533 days is determined to be the actual number of days that the issuance of the patent was delayed, considering the 533 days over three years and the 377 days of examination delay. Accordingly, 156 days (533 - 377) should have been entered at issuance for a total Office day of 533 days.

As such, patentees are entitled to a patent term adjustment of 308 days (377 days examination delay + 533 days Three Year delay reduced by 377 overlap - 225 days for applicant delay).

Accordingly, the patent term adjustment indicated in the patent is to be corrected by issuance of a certificate of correction showing a revised Patent Term Adjustment of three hundred and eight (308) days.

The application file is being forwarded to the Certificates of Correction Branch for issuance of a certificate of correction in order to rectify this error. The Office will issue a certificate of correction indicating that the term of the above-identified patent is adjusted by three hundred and eight (308) days.

Telephone inquiries specific to this matter should be directed to Shirene Willis Brantley, Senior Petitions Attorney, at (571) 272-3230.

A handwritten signature in black ink, appearing to read "Nancy Johnson", with a long horizontal flourish extending to the right.

Nancy Johnson
Senior Petitions Attorney
Office of the Deputy Commissioner
for Patent Examination Policy

DRAFT

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT : 7,504,398 B2

DATED : March 17, 2009

INVENTOR(S) : Bernat Vidal Juan, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

[*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by (152) days

Delete the phrase "by 152 days" and insert – by 308 days--